

program to recognize those companies that are utilizing the WBRO and have given us good documentation that there are procedures in place that will assure a person with celiac disease that they are making a choice by purchasing this product, that it is free of wheat, barley, rye and oats and everything else.

These are the general terms of the license. We say that it is generally free in product, processing and packaging. Everything is kept confidential. Confidentiality I think is very important in this type of communication between consumer and the company. And, this is the seal of agreement.

Questions and Answers

DR. SCHNEEMAN: Maybe we will take just one or two quick questions, if there are some, and then we will save the others for discussion.

DR. KANE: Thank you very much. Rhonda Kane, FDA. Mary, with your certification program do you ask them what parts per million their products have to stay below for any sort of test

for gluten, or do you require them to have a test with the results shared with you? What is the scoop there?

MS. SCHLUCKEBIER: We require them to submit some product and we will go pick things up from the grocery store periodically. Depending, again, on the processing, they are assured that it is in place. If it is a dedicated plant and they have only two products our testing requirements are a lot less than if they have 20 products. They have dedicated lines but in a somewhat segregated area. So, it really depends on the company itself and what procedures they already have in place and they may already be testing. If they are, then we do ask for copies of those and we do also do our own independent testing. We will also do on-site if the situation is one where that looks like a prudent choice for helping people with celiac disease that it is a product that is staying consistent with no WBRO.

DR. KANE: Do you have a cut-off point though? In other words, do you use 10 parts per

million or below as receiving permission to use your seal? Or, can it go higher?

MS. SCHLUCKEBIER: I really don't see any time when it would go higher than 10 parts per million. It often might be lower. Many of the products that we are testing where we have tried at 3 parts per million, they are doing beautifully. It is not detectable at all at 3 parts per million.

DR. KANE: Thank you.

MS. SATCHELL: Felicia Satchell, FDA. I wanted to ask about your CSA gluten-free product testing and if there are any criteria that manufacturers have to meet in order to get their manufacturing information or products listed in the manual.

MS. SCHLUCKEBIER: Right now, because there is no FDA definition, we send the manufacturer our list of what we consider necessary to assure people that it is a product that is free of wheat, barley, rye and oats. Most companies are very, very good at voluntarily saying which of their products are the best choices. We can't test

all of them and we don't; we take their word for it. Often when we get communications from a manufacturer who wants to be in it, you can kind of tell--again, those red flags. There are some things that just don't seem right here. So, we will do some extra checking and we will ask for more documentation.

MS. SATCHELL: A follow-up question, do you know if these products that are included in your manual labeled as gluten-free are actually on the product package?

MS. SCHLUCKEBIER: Probably very, very few of those are marked gluten-free. Those companies that do provide it are basically a niche market to those who are trying to stay free of wheat, barley, rye and oats for any reason. We do have an area in the back that is a vendors' section where we give the company an opportunity to share a few paragraphs about their company that helps provide the people with celiac disease additional information to make their decisions.

DR. SCHNEEMAN: Can you hold your question

for later discussion, please? Our next speaker will be Miss Pamela Cureton, who is a dietitian who works at Celiac Research Center which is affiliated with the University of Maryland, located in Baltimore, Maryland.

Celiac Research Center

MS. CURETON: Good afternoon. I happen to be one who had a great lunch this afternoon so I thank you. It was delicious. My name is Pam Cureton. I am a dietitian at the Center for Celiac Research at the University of Maryland.

Recently, in July, we presented a conference. We did a conference for both professionals and patients. It was about a day before the conference was scheduled and we were running around, extremely busy, trying to get ready to put on the conference, when we got an e-mail from Rhonda saying, by the way, do you have any questionnaires, surveys, any information that we might be able to use in helping us answer our questions? So, I got an e-mail from Dr. Fasano saying, hey, this is a great opportunity. I said,

well, I had a couple of hours slated for a little sleep; I can forego those. So, quickly we put together a survey trying to look at some of the questions that the FDA is looking at in the Federal Register.

So, this is just a quick summation of what that survey was. Taking a look at who completed our survey in demographics, you can see that these are all members of CSA because they meet the same profile. The sample size was about 57, mainly female. People completing the survey were aged in a range from 11-78 years old. Actually, a person on a gluten-free diet ranged from 3-78. They are of a higher income level and had at least some college. They are predominantly European American. And, about a half of them had at least two years on a gluten-free diet but some were just newly diagnosed, less than a month, and some for more than five years.

I wanted to know how carefully they thought they were following their diet, how strictly did they follow that diet and how

compliant were they. About 53 percent said that they never ingest gluten. As part of the question we asked are you concerned about questionable ingredients or cross contamination? And, these people felt that they did not ingest any gluten and there was no concern for ingredients or cross contamination. Thirty-seven percent, however, were trying hard to follow their diet but weren't sure about these questionable ingredients or if they were getting cross contamination in their diet. Five percent actually knowingly ingest gluten.

In trying to answer question number eight talking about ingredients that should not be present in gluten-free foods, I also found this one interesting when we just listed ingredients that somebody with celiac disease might question. So, there are a lot of things on this list that are perfectly safe and really don't need to be questioned. But you can see that a lot of our respondents were concerned. Overall, it shows that people are very confused about ingredients, what goes into ingredients, and whether it contains

gluten or not. For example, starch, as this committee is well aware--if the word starch appears on a food label, it is from corn, therefore, it is completely safe to eat.

Also, some known gluten-free or non-gluten-containing grains like millet and buckwheat, again, are of concern to some of our respondents. Things like distilled alcohol and vinegar are still concerns. So, people have a lot of questions about what is on that food label and what is in those food ingredients.

So, we asked what does gluten-free mean. Are we talking about no detectable levels? Are we talking about trace amounts that are probably safe to eat? Or thought to contain gluten and definitely contain gluten.

There is no surprise here. Seventy-one percent of the respondents felt that a food item labeled gluten-free should have no detectable gluten. There should be no detectable gluten in the product. A few responded that there could be trace amount and they would consider that safe to

include. Only two percent said it may contain gluten.

Again, the same question was asked, what should it mean? You have your perception of what you think it means; what should it mean? Again, very much similar response and 83 percent reported it should mean no detectable gluten; 17 again reported that they would consume it if it had trace amount and feel that it would be safe to consume. So the perceptions of what people think gluten-free means and what it should mean are virtually the same. An overwhelming amount say that there should be no detectable gluten.

At looking again at trying to identify foods with gluten, and I think it was question number nine, we asked how consumers identify packaged foods that do not contain gluten. When you are reading labels how do you identify those foods? Of course, reading labels was number one. Our respondents could check more than one answer so they could check from a list of questions which ones they would use. Thirty-two would rely on the

food labeling gluten-free; 25 would call the manufacturer. Other choices which were not selected would include asking healthcare professionals, like dietitians and physicians--that made me feel good! We also asked about risks and product guides. Those were other selections that people used to find out if their food had gluten.

Question number ten refers to packaged foods like consumers with celiac disease purchase or consume are primarily or exclusively those foods labeled gluten-free, so kind of what influences the purchase. Only 24 respondents reported that they would rely on those gluten-free foods, while others would rely on the manufacturer or, again, rely on the safe food lists that are published or on the internet. They would use those as reference.

We did ask how likely they were to purchase the food if the food was gluten-free, if there was nothing on the label that indicated that it contained gluten but it was manufactured in a plant that also manufactures other foods that do contain gluten. So, how likely were they to

purchase that food? They were evenly divided on either extreme. Only nine percent said they absolutely would and only nine percent said they absolutely would not. So, the majority of the people were in the middle and would probably purchase the food if the food was gluten-free but still was manufactured in a non-dedicated plant or where other gluten-containing grains are.

Obviously, there are limitations to this study. It may not generalize well to all of our celiac patients. It was a sample of convenience and, again, these were predominantly high income, well educated Caucasian Americans participants with an average age of 47. So, it was a small sample size and based on self-report. Thank you.

[Applause]

Questions and Answers

DR. SCHNEEMAN: Do we have some questions?
Yes?

DR. LUCCIOLI: I have a question on a slide where you say what does GF mean. You have a trace amount of gluten and in parentheses you have

less than 10 mg.

MS. CURETON: It should be 10 parts per million

DR. LUCCIOLI: Okay, that answers that. What does the consumer understand? Do they understand the significance of the level 10 mg/kg or that it also is a factor of how much they eat?

MS. CURETON: Based on clinical experience in a clinic when I instructed patients, they basically have no clue as to what a part per million is, what a milligram is, how much you can eat, that there is anything in the foods that they eat that is listed gluten-free. They are assuming there is nothing there; that they are getting any source of contamination when they are reading their labels and following the recommendations, and how much they can eat. This doesn't enter into their thought process.

We have patients who are more sensitive to gluten and we have a hard time getting the antibody levels down to normal. So, some patients can do the basic diet, follow it carefully, read the

labels and do quite well. But there are those that are more sensitive and we have a hard time getting their levels down. Those are the patients that I spend more time with talking about those types of issues--how much of the gluten-free products they are getting. I try to explain to them there could be some contamination or low levels of gluten that they are very sensitive to, and they are very surprised when they hear me say that.

DR. LUCCIOLI: Thank you.

DR. KANE: Rhonda Kane, FDA. Thank you very much, Pam. I had a question about gluten-free. You talked about no gluten, but as far as the grains that they consider being sources of gluten, are they the typical ones we have heard about from others, and what about oats? Could you elaborate, please?

MS. CURETON: They would be the typical grains. Again, the patients that we see are well aware of wheat, rye, barley. I am questioned frequently on oats. But wheat, rye and barley are the standard grains that they are well aware of.

DR. KANE: And does that include the crossbred hybrids like triticale and also other varieties or other species within the triticum genus with kamut, spelt durum wheat, etc.? Are they including those too?

MS. CURETON: I think a lot of them, like me, didn't even know what triticale is--I can't even say it--before I started looking into celiac disease, and kamut and all of these things. I don't think most people knew what they were. Those things they are less aware of, and spelt is still a big one, as we commented on earlier. Health food stores are promoting gluten-free diet being okay to have spelt and a lot of people are very confused about that.

DR. KANE: What about the oats issue? Are they including oats or not?

MS. CURETON: They are not including it; they are asking. They are asking for permission. When they come to see us they are asking for permission. At this point we do not allow oats at our center. There are other centers that do. I

basically give them that information. I tell them that we are not recommending at this time and I tell them other centers are, and they are okaying it, and what I ask them to, if they do decide to make a decision to try oats, to please let me know so we can then follow their antibody levels to make sure that they are doing it safely. So, we would just follow those patients if they choose to do that. We, again, present them with the latest and what our opinions are and just ask them to tell us if they are going to try oats and then we will follow them for their antibody levels.

DR. SCHNEEMAN: Thank you very much. Our third speaker for the panel is Miss Anne Lee, who is a nutritionist who works with the Celiac Disease Center which is affiliated with Columbia University located in New York City.

Celiac Disease Center

MS. LEE: I want to thank you for inviting me. I am very honored and, indeed, pleased to be part of this momentous occasion in helping the FDA determine what should be included in gluten-free

labeling and to help direct that.

Today we are going to be talking about different topics that need to be addressed. Actually, Tricia Thompson's name is on the program also. She is the lead author on a diet survey that we will be looking at. What we have done is combine Tricia Thompson's article on the survey of gluten-free food consumption, in addition to surveys that we are doing ongoing at Columbia which look at consumption patterns, the price of gluten-free food, in order to pool the latest research information that we have together to better address the various questions the FDA has asked us to look at.

In the gluten-free diet survey we reviewed the food records for 47 adults, 39 females, 8 males. Again, this seems to be representative of the population of people with celiac disease. It was interesting in this population that as we looked at their consumption patterns and the types of foods that they ate that across gender they tended to eat the same types of foods.

What was also very interesting is that the largest group of foods that they tended to eat were the prepackaged, pre-prepared foods that were labeled gluten-free. The patterns also noted that there was a large influence of corn-based products, particularly snack type corn-based products, like the chips, the savory snacks, and only two participants out of the 47 actually consume the other gluten-free safe grains. There were two that use bean flour or millet on a routine basis.

So, when we look at these consumption patterns, we are finding that many people relying on the labeling of gluten-free and relying on things that are safe. And, I think that is an important thing to note.

The other thing we found is that the type of food groups, whether it be sandwich bread and pastas or corn tortillas, also had a determining factor on whether or not the product they consumed had a gluten-free label, and it was depending on the particular groupings of food whether or not those foods were labeled.

The foods that are in the sandwich bread group, which included muffins, pizza crust, pretzels and those things predominantly, these foods were all well labeled gluten-free and participants overwhelmingly chose the ones that were labeled gluten-free over those that were not labeled gluten-free, and the labeling was prominent on the packages, as you can see. It was front and center and highlighted, which we feel was an added bonus of security to the patients buying these products.

In the pasta group, again, we find the same sort of purchasing patterns. Again, these foods tend to be specialty food items. They were done in designated facilities. They were prominently labeled as gluten-free, and most were labeled gluten-free, not all, but the list of ingredients was the second determining factor in this group. Again, the labeling tended to be prominent rather than being small or on the back of the package, which was an influencing factor, and it was everything from saying gluten-free in

the middle of the bag to just the universal symbol that is often used on the European products.

In the pasta and ready-to-eat cereal, the group of products in this main category that were not as prominently labeled were those that we call more ethnic type foods, like the Asian rice noodles, and these foods tend to be naturally gluten-free. They are only made with rice or buckwheat so, therefore, are gluten-free. These were the products in this main heading that were not labeled and these were the ones that the participants used the list of ingredients to determine their safety.

The next group of foods is snacks and crackers, and this was a product area that actually presented some problems. This was a group that was one of the largest food consumption groups overall. When we look at all the different products that our patients and clients were, consuming, the snacks and crackers and these prepared foods actually comprised over 50 percent of their daily intake.

Now, as a dietitian, you know, red flags

start going up, and when we see that someone's grain and carbohydrate intake is over 50 percent of snack foods, it makes me be very concerned about the nutritional content of the diet overall.

Indeed, Tricia had done other work that notes that the nutritional intake and nutritional value of someone on a gluten-free diet is not meeting the standards we need.

One of the things too in this area of products is that we find much mislabeling. As you can see, one brand of the rice crackers was labeled "no gluten added" on the front and on the back it says it contains trace amounts of wheat. What is a consumer to do? Which side of the package do you believe? So, standardized labeling would help alleviate a lot of that.

As we said, the corn products were one of the areas that were heavily relied on. Again, it was a lot of the pre-prepared snack types of foods that, again, raise some concern. As many of these products are considered naturally gluten-free--a corn tortilla for the most part is corn and a

little bit of salt so it is generally safe. However, the heavy reliance on corn-based products also has a negative impact on the nutritional quality of the person's diet. We are missing fiber; we are missing the iron; we are missing other B complex vitamins.

The other area besides the corn and snack food, as we said before, is the large selection of frozen prepared foods that many of the participants use. The good piece of information on this is they chose foods that were clearly labeled gluten-free but, again, there are so many questions about nutritional density of those choices.

Based on these findings. we were concerned that with this type of an intake and with knowing that gluten-free labeling was an important factor in these consumption patterns, we wanted to look at the next step. What is it that makes a consumer or a client determine whether or not to buy a product? So, again as Pam had done, we did a survey of about 57 people who came to see us at the office and the Celiac Disease Center and asked them--we gave them

a short, little survey--what was it that made them decide to buy one product over another.

One of the outstanding pieces of information we got from this is that 100 percent of the participants, 57/57, said that if there were two products side by side with identical ingredients and one was labeled gluten-free and one was not, they would purchase the one that is gluten-free, which is a wonderful endorsement for the labeling. However, it also brings to mind the concern of does that make one had of broccoli safer than the next? So, I think we need to keep in mind that there is an overwhelming need for labeling, but labeling of the appropriate product.

I had one woman tell me, well, I know that this can of tomatoes is okay and it is better than the other one because it says it is gluten-free. There is really no foundation for that. A can of tomatoes is a can of tomatoes. So, we know that there is a drive by the consumer, by our patients, to look for that safety in the labeling but we, as the industry and we as the professionals in the

health field, need to also direct them and teach them which way to go.

We did find that the presence of the gluten-free label did, indeed, have a very huge impact. When a label was not available on those products--again, the savory snacks, the crackers, the naturally gluten-free products--the second thing that the clients look for, in a 2:1 ratio, was the list of ingredients. They will look down the list of ingredients and try to determine from that whether or not the product is gluten-free.

What we found, however, is that there are many questions. Is spelt, indeed, what or not? What is triticales? And, where does kimwa fall into place? So, they try to decide from the label but more information is needed there.

Now that we are going to be better understanding what is influencing our patients' and clients' practices, we also need to know how to teach them well. For this part of the presentation I wanted to highlight the ADA, the American Dietetic Association, manual and the client

education material that is available for all dietitians because I think not only do we need to educate the consumer, but we need to educate ourselves so that we also know the grains and things that we are going to be teaching them about.

However, at the time of this presentation the 2004 ADA manual is the one that we are showing you here. The 2005 edition, which will reflect the 2004 food allergen labeling law is in the last stage and may be ready for the September 19 docket deadline, but at this time it is not. That one would give a better picture of what we really need to teach our clients and how we really need to direct them and steer them through the food labeling and the ingredient list.

We would be able to say that malt is still something to worry about because it is barley based, whereas the modified food starch is going to be corn based and it will say it so that we will be able to better teach them things to look for there.

As we said, barley and rye will continue to be an issue in the 2005 edition, but that is

something that we will make sure that our client is educated on. The ADA manual does tend to be client-centered so that we give them the tools that will be able to give them that shopping list, that hand-held kind of piece of paper to take to the store so they can make those informed decisions and can maneuver through the various products, with it be a rice cake, the kind of thing that might not be currently labeled and the ingredients may be difficult to get through.

In all of this, we realize that we are purchasing many products, that we have increased availability of food, increased availability of labeling and increased availability of foods in the various vendors, whether it be a supermarket, a health food store.

But we found, as we are looking at different patients and they are reporting back to us, that in what was influencing their purchasing practices there was an underlying tone of "but I can't find it" and "I can't find that." If you started asking them where they shopped and how they

purchased their food, we found overwhelmingly that they tended to do it in the grocery store, the health food store, online or through specialty vendors. But this raised the question to me--and we actually did a survey of the difference in cost of the products in these four different spaces. The regular grocery store availability depended upon where they were. We surveyed stores in Portland, Oregon, Rapid City, South Dakota, Chicago, Illinois, New York and Atlanta, Georgia. What we found is that depending upon your location--and I can guarantee you know exactly which store had products and which one didn't--that determined what that client was able to obtain. The patients who were looking for things in the Midwest, in the Rapid City area, they had to go online. That was the only choice they had. That brought up the question to me, because the online products tend to be more expensive than those products, if you can find them, in the local health food store or grocery store.

So, in addition to the labeling that our

clients have to decipher, we also have the additional burden of finding the food and the economic cost of it. So, maybe if the foods were labeled in the regular grocery store, those rice crackers and things, it may increase the availability of food to these people in these other locations. We are fortunate on the East Coast to have a great availability of food but that is not true for many people across the country. And, we get calls frequently at the Center from people in Iowa, in South Dakota asking is it safe to eat X, Y, and Z product? And, we have to try and direct them as best we can through those ingredients because that may be all that is available to them.

We looked at two different groups because those tend to be the largest consumed products, the gluten-free pastas, as we have seen, and the gluten-free bread, and in both cases there was an increased price for buying the product online. What we did is we took two products and looked at them both in the health food store and online, and this was the difference in cost even before we

added in shipping and handling. So, the concern is that for those consumers where the market may not have quite caught up to them yet there is not only the burden of reading those labels but the economic one, as we said.

The final thoughts are that for our clients with celiac disease we do want to encourage them to consume a wide variety of foods. They do include many various products, both labeled gluten-free and not. Those that are not labeled gluten-free, they try to obtain those that are manufactured in dedicated facilities. That is not always possible. There is a strong preference to purchase the foods that are labeled gluten-free when available and when possible. Many have reported that it is difficult to determine the gluten-free status of a product that is not clearly labeled. Thank you very much.

[Applause]

Questions and Answers

DR. SCHNEEMAN: We will have some specific questions for Anne. Then, if the other panel

members could come up we will have the general panel immediately following. So, if we have some specific questions right now? I will let Don go first.

DR. ZINK: Don Zink, FDA. You talked about looking for products made in dedicated facilities. How frequently do manufacturers label or indicate if a product is made in a dedicated facility, and how do they do that?

MS. LEE: Often through advertising. There are certain manufacturers that do state it is a dedicated facility. It may be on the label. It may be in the advertising in various magazines and journals. But, again, the consumer is left to try and find that out before they can even purchase the product.

DR. ZINK: I guess a follow-up, is it desirable? If you have gluten-free labeling, is it desirable to also have some sort of labeling if it is in a dedicated facility or not? Does that improve comfort level?

MS. LEE: It would improve comfort level

but, indeed, if we had uniform gluten-free labeling, my understanding would be that it would meet those standards and the additional labeling that it is a dedicated facility would not need to be on it because it is already going to meet the standards of being gluten-free.

DR. PARK: Doug Park, with FDA. I noticed oats is missing in your presentation. Would you like to explain that?

MS. LEE: We say that oats are okay, with this caveat, because oats are a wonderful grain and scientifically it is gluten-free. It is the milling, the handling, that cross contamination that is an issue. From work that was done by Colin and Thompson who have looked at the issue of gluten contamination in oats, there are a couple of oats that are available that we feel do meet those standards. We have looked at the research out of Europe and we really feel that including clean oats in the diet enhances the diet. It helps add those nutrients back that right now are sorely missing. However, we beat our patients up a little bit.

They can't start oats until they are symptom free. We are not going to add a new twist into the diet unless we know that their antibody levels have come down; they are symptom free. Then if we add oats we know the variable we are adding. We add oats in from the two different providers that we say are safe and then we follow up with them both with antibody testing as well as symptoms. If there are any changes there are no more oats. We instruct them very, very carefully. It doesn't mean oats on any label; it is specifically the can of oats that are clean, designated oats.

DR. PARK: Thank you.

MS. LEE: You are welcome.

DR. KANE: Anne, I have a question. You said several times in your slides that the presence of a gluten-free claim or symbol strongly influences purchasing choices of people who have celiac disease. Is that correct?

MS. LEE: Absolutely correct.

Specifically on the two products side by side that were identical based on the ingredients, if one is

labeled gluten-free and one is not, in our survey 100 percent of the respondents picked the one labeled gluten-free.

DR. KANE: Okay, I am going to take you to the next step because you gave a very good example about canned tomatoes--

MS. LEE: Yes.

DR. KANE: --say, all canned tomatoes, if they are strictly canned tomatoes with tomatoes and salt and possibly another second ingredient but it is tomatoes, period--

MS. LEE: Right.

DR. KANE: --if they are all inherently gluten-free and one has a gluten-free claim and the other doesn't, just because they don't choose to put it on there, not that it isn't; it is identical--

MS. LEE: Right.

DR. KANE: --in your opinion, what would be a way to make it less confusing for consumers who are looking to make the right choices and not being concerned that one brand is okay but the

other brand isn't, and get the message across that all of the same type or category of food is gluten-free whether they have a claim or not? So, what would be your suggestion if somebody used a claim of gluten-free to kind of rectify that?

MS. LEE: What we do, and I am sure Pam does something similar with her patients too, we try to educate the patient, because we start there, that there are certain foods you need to be careful of. Things like your fruits and tomatoes, if they are just inherently that product--the can of tomatoes, the head of broccoli, the frozen carrots--that naturally is gluten-free. It does not need a label. What we would recommend is that the manufacturing community follow the same thing. There is no need to say a tomato is gluten-free. It is gluten-free.

Where the labeling would help is on those grain products that do present a question as to whether or not they are gluten-free. If we could recommend that the law would include those products that would raise a question--the pastas, the

breads, the cereals, the crackers--because those are the things that we need to help identify for our patients. A broccoli is a broccoli, is a broccoli. It doesn't matter whether it says it is gluten-free or not.

DR. SCHNEEMAN: If I could maybe just clarify what I think Rhonda is getting at, so, if a person still chose to do label their broccoli or tomatoes because they feel it is a truthful statement, is there other information that should go on that product to help consumers or the clients that you are concerned about, or is it okay for them just to do it that way?

MS. LEE: It is not false labeling. It is okay for them to label it. It may be misleading in that it may make the product appear enhanced even though it is still the same product. I don't know how you would, you know, differentiate on that.

DR. KANE: Are there any different ways that a product could include a gluten-free claim but the way it is worded, would that help? And, do you have any ideas of how additional wording should

be added or, in other words, word it one way if there is a potential that it could contain gluten and this is special because the processing is there, versus all of the same foods in the same category is gluten-free--all milk? So, what would you get across to let people know that all milk is gluten-free and not just certain brands?

MS. LEE: Naturally gluten-free. I think the terminology that this food is naturally gluten-free, just by the nature of its composition, may be the way to go. Whereas, a rice cracker or a pasta is not naturally gluten-free and that is a special manufactured product. So, if it is labeled that this is a gluten-free grain or this is a gluten-free product versus a naturally gluten-free product may be the way to differentiate that the tomato is the tomato but the pasta is a rice-based pasta and, therefore, a different type of product.

DR. SCHNEEMAN: Would that help?

DR. KANE: Yes, that is very helpful.

Thank you.

DR. SCHNEEMAN: We can have your question

but if we can get the other two panel members to come up? Felicia, do you want to go ahead?

MS. SATCHELL: Felicia Satchell, FDA.

Actually, this question is directed at both Tricia [sic] and Pam. It goes back to the statements that you made about patients who are eating oats. I think in your case, Pam, you advised that if they do that to let you know and that you would continue to monitor their levels. I guess I just wanted to know in cases where you have patients that have eaten oats, have they had any problems as you have monitored their levels? Have they been able to maintain the oat diet? And, in your case, Pam, the oat products that they ate, were they shelf products or were they specially marketed products, similar to the ones that Tricia's patients have consumed?

MS. CURETON: Generally our patients don't. I don't see a lot of patients who do eat oats. Our patients are asking permission before they would do that. I have seen so few that I don't think it is really significant. I have had I

think one patient in the last six months that came to us already on oats. It so happened that their antibody levels were normal and there were no symptoms. It was a child and they were growing well. I did not pull them off the oats. They were using I think McKane's oats, but not another product.

MS. LEE: Anne, from Columbia University. When a patient comes and requests oats there are a couple of types of patients in whom we actually encourage the inclusion of oats. Our patient population is predominantly adults. We have several males. As a normal male, we have cholesterol issues and we find that including the higher fiber grains--oats, kimwa, buckwheat, millet--that is a way to help enhance the nutrient density and fiber content of the gluten-free diet. But, again, we only recommend two types of oats. It is not the commercially prepared oat bars or oat cookies. And, we do closely monitor them.

DR. LUCCIOLI: Stefano Luccioli. What percentage, would you say, of your patients

eventually have to drop oats from their diet, or haven't you had really anybody?

MS. LEE: We have had one or two people that have not tolerated them well but it is really few. Interestingly, it was two adults. The kids that we have that are doing oats, as Pam's patient also--they are thriving; they are thriving, which is one gentleman and one female. So, it didn't seem to be a gender issue, just an individual tolerance. Again, when we introduce oats we do things, as we do with any trial type of a diet, we don't let them go gang-busters. I feel that many patients do react to oats initially if they go from a very low fiber diet, which the traditional gluten-free diet can be, very devoid of fiber, and if they add a lot of the alternate grains that are very high fiber, you can get a reaction. Anyone would get a reaction to that dramatic increase in fiber. So, we instruct them to add the oats slowly and monitor. They even do it as an alternate day until we establish the tolerance for the oats and the other grains also.

DR. LUCCIOLI: And does your clinic have a policy on the wheat starch since that was also another issue that in Scandinavia they tend to recommend as well?

MS. LEE: They do. We don't recommend wheat starch at this time.

DR. LUCCIOLI: Is there a particular reason for that?

MS. LEE: We feel that for oats there has been enough documentation for that to be considered safe. The wheat, starch we don't feel we have enough information on that as yet.

DR. LUCCIOLI: Just one more question probably for the panel. I think we had a recent meeting on thresholds, about a month or so ago. And, it was proposed that maybe a two-tier labeling method could be used, kind of what Rhonda was saying before, where maybe, you know, where you could have gluten-free and really gluten-free--I mean that kind of jokingly, but do you think that your patients or members would appreciate something where a strong statement would say that this will

not have gluten, whereas another statement would say, well, we can't guarantee that this doesn't have traces of gluten. Do you think that that is something that consumers with celiac would want?

MS. LEE: Anne Lee. I think generally our patients are looking for any definition on the packaging of the foods that they purchase. If it is a two-tiered effect, with the understanding--and we can instruct them as to what is really gluten-free and what is gluten-free but in a non-dedicated facility, I think that gives them the information so they can make an educated choice. I think they are clamoring for that type of information and for that security even if it is on a two-tier or three-tier basis that this is absolutely gluten-free; this is gluten-free but not in a dedicated facility; and these tomatoes are perfectly fine because they just are perfectly fine, they would love it. And, I think that it would enhance their comfort level and their ability to expand their diet from where they are at this point in time.

MS. SCHLUCKEBIER: This is Mary Schluckebier, from CSA. I think that an area where you could absolutely be sure that this product is totally, unequivocally absent of any barley, rye, oats, or anything, would be in a hospital when you aren't choosing your own food and you are already under a stress condition. I think many of our patients express that their experiences in hospitals, working with a dietitian and someone else as a caregiver, either hospital staff, training table person, a child care facility, for those people to be able to make choices that they know are unequivocally very precisely meeting the prescription of the diet, I think is a place for that.

DR. SCHNEEMAN: Actually, I would like you to also comment--I was curious about your certification system, do you also get reporting from consumers about adverse events, about things where it was certified but they had some sort of reaction? Do you get that information from them?

MS. SCHLUCKEBIER: Right now there is very

little certification program out there anywhere except companies doing some ELISA on their own. Yes, we do get information from members who tell us that they have had a bad experience with something. What we do, we have them send the product. We will have it examined. What we try and do, if they have used some of the product, we do also ask them if they could go and purchase a product with the same oat in it or we try and purchase one locally that is the same company to see what kind of results we are getting, and we do pay for that. Generally, the products have come out with a low level of detection. There are a few cases. There was a loaf of bread and it came out over 5,000 parts per million, which means basically a wheat bread.

DR. PARK: Douglas Park, with FDA. This is for Mary. I am glad you had your previous question because that is a segue back to what I wanted to go into, your certification presentation, part of your presentation. In your certification do you actually visit the facilities and conduct an inspection to confirm that it is either dedicated

or addressing the issues of trying to avoid contamination?

MS. SCHLUCKEBIER: It depends on the product. We can have a representative of CSA, because we have chapters and members all over the United States, so generally we can have a team with a check list go in and to an on-site observation. There are times when we have had the company make photographs for us to have on file. We do have a relationship with a company that does certification for some other areas that has agreed to go in and follow our protocol to do on-site visits.

DR. PARK: Along that same line, do you audit the companies on a regular basis, annually, semi-annually, whatever, to confirm that they are still preparing a product and then follow-up with actually testing of the product?

MS. SCHLUCKEBIER: Absolutely. Again, the calendar of those events does depend on how much flexibility they have; if they have changed suppliers. Yes, some of those things would create a testing earlier than would be normally scheduled.

DR. PARK: Thank you.

DR. LUCCIOLI: As a follow-up, I guess I want to get a little bit more insight on quality of life of celiac patients. I have read some studies where there supposedly is no change in their quality of life, where it seems like once a celiac patient knows what they need to do they are content. Do you get a sense that this is not the case? That they are screaming to you to have more products available, or is there a subset of people who would be willing to take some risks just to have more products to consume?

MS. SCHLUCKEBIER: This is Mary, at CSA. I will tell you, it depends on age. It depends on how long they have been diagnosed. We have an 86 year-old member. I think she was number 16 at NIH when she was in her 30s and just had a child, and was in Japan and was diagnosed with celiac disease, as was the child later. She is 86. She gets very unhappy when the 40 year-olds no longer ask her to play tennis with them. She would love to have oats back in her diet. She would love to be able to

take some risks, and she probably takes more risks than I do. She has had over 50 years on the diet. She is very comfortable with what she can eat and she probably has a more varied diet than most non-celiacs in the U.S.

DR. SCHNEEMAN: Do you want to comment?

MS. CURETON: I would say, based on the time that I have been working in this area for the last 12 years, when I first started so few were diagnosed 10, 12 years ago I think your diet would be very limited and there wasn't a lot to chose from. The products today are far beyond what was available 10 years ago. So, somebody diagnosed today I think has wonderful choices, and we supply them with a list of manufacturers and vendors so the quality of their products is equal to what we would use for wheat products. So, I have been very pleased with the products. You have wonderful tasting products. Probably the area that is a problem is the cost and convenience. They are usually mail order and there are not a lot of times you can get them right off the grocery store shelf.

You have to make a separate trip to the grocery store or you have to order them by mail. But the quality of the products is just phenomenal. So, I think those who are diagnosed today I think are having a better quality of life of life and it is easier to follow the diet because of what is available.

MS. LEE: If I may--it is Anne Lee from Columbia University. We are actually finishing up a huge quality of life study based on the impact of symptoms as well as the gluten-free diet. What we have found does concur with that, that in that first year from the onset of diagnosis and the first year on a gluten-free diet there is a wonderful increase in quality of life, and people feel better; they are symptom free; they feel that they are going to live. So, there is a very huge upturn in their perception of general health and quality of life.

In two to five years since diagnosis it tends to drop back down both in males and females. The feeling is that at that point they now have

gotten to the point where they know they are going to live. They know they feel better, but the routines of daily life become more of a burden. It is that extra trip to purchase the loaf of bread.

Travel and business meetings are one of the major complaints and issues for the males in the population group. Females have found that traveling and dining out was just a burden where 30-40 percent, depending on age category, of females with celiac disease would choose not to dine out because it is too much of a burden.

So, there is an issue with quality of life. Labeling will, indeed, help some but, hopefully, down the road not only will we get labeling under control but maybe even get menus and things done because these are the areas of their life that people without celiac disease don't think twice about, for stopping for the coffee and something but for someone with celiac disease it requires thought, preplanning and purchasing that product and, hopefully, that product is appropriately labeled.

So, there are studies on quality of life. The ones out of Europe tend to have a better rate overall of quality of life on a gluten-free diet, but the question that comes up with that is, is it because they allow the oats, the wheat starch and the labeling is better? We don't know. So, we are hoping to do some studies with Colin to compare the two populations.

MS. CURETON: This is Pam. The other thing too, we talked about patients earlier that took 11 years to diagnose, those patients are very sick and felt very bad. Once they started the gluten-free diet it was a huge change in their life. Those patients would not take a risk. They would not add anything back to their diet because they know how sick they were. But with better diagnosis or screening and a person who is asymptomatic, that is the type of person who would have a much harder time with the quality of life and issues that they are faced with, but those that were very sick would not touch gluten in any shape, form or for any reason.

DR. SCHNEEMAN: We need to start finishing up this panel so I am going to have one more question. Felicia?

MS. SATCHELL: Felicia Satchell, FDA. This question is really not meant to put you on the spot but, just in your professional opinion and experience, a definition for gluten-free should or should not include oats?

MS. LEE: Anne, from Celiac Disease, Columbia. I will start. I think it should, but it should define what the level is and it should define that the oats need to be clean. So, I think if we can define gluten-free with the appropriate level of parts per million, and we can have oats labeled as clean I think it would enhance the gluten-free diet and alleviate some of that burden of illness for those patients. I know that is out on a limb but I honestly believe it makes a difference to our patients.

MS. CURETON: This is Pam. I think at this stage there is a lot of confusion still, and I do agree they are technically gluten-free from the

standpoint of the oats themselves. But with the contamination issues and some of the other tolerance issues, at this point I would not include them.

MS. SCHLUCKEBIER: Mary, at CSA. At this time I wouldn't include them. If oats are in a product at some later date, again, they are probably going to be clearly labeled as oats, and at some point when there is a standard, to add oats if it has passed all the rigors of study, I don't think it would be difficult to add that. For the first few years it may need to have some additional notes on labels with oats that would also include a gluten-free label so that people would not be confused. But at this time I just think it is premature to add oats in with gluten-free.

DR. SCHNEEMAN: Of course, some of our panels may not understand the difference between difficulty from a scientific point of view and difficulty from a rule-making regulatory point of view. There is a difference. I have only been here a little bit over a year and I have learned

that lesson.

Again, thank you very much. This has been a wonderful panel and really helped address many of the questions that we have.

[Applause]

Now it is time for our afternoon break, which is scheduled for 15 minutes. We are going to ask you to be back as close as possible to 3:15. I will give you two extra minutes. I do want to make sure that anyone who has signed up to speak, you need to do something during the break. So, if you pre-registered to speak before the meeting today, please see Jean Latham. Jean is right back here with her hand up. For those who registered on-site today, please see Laretta Carey. Laretta is right back there, waving her hand. So, we can get it set up to start right after the break. Thank you.

[Brief recess]

DR. SCHNEEMAN: I think we really need to get started. We have several individuals who have asked to provide comments so we want to make sure

that we allow time for that. I am asking our FDA panel to take a seat at the front so that we can hear the comments. As indicated before, each of you will have five minutes to make the presentation. It is very important that you identify who you are and if you are representing a group or speak on behalf of a group. Please identify that affiliation. We will keep track of the time here and, hopefully, we can keep it well within the time. I think we are going to start with the group here.

Public Statements

MS. HOPKE: My name is Maryrose Hopke, and I am representing the Celiac Disease Foundation. CDF is a national organization that strives to promote awareness and build a supportive community for celiac patients, families and healthcare professionals. The information we provide is evidence-based, not anecdotal. On behalf of CDF, we thank members of this FDA committee for the opportunity to express our opinion on this important subject, gluten-free

labeling.

We all understand that celiac disease is a life-long disease that has no cure. Yet, as we are also aware, it can be effectively controlled through a gluten-free diet. Confirmation by the NIH that 1/133 individuals in the United States are affected means that, consequently, two to three million consumers will have to watch everything they eat and drink and every medication they take.

The celiac community is at a distinct disadvantage at this time to properly answer the questions posed by this committee: What should gluten-free mean on a food label? How does the celiac identify foods that do not contain gluten? How much time do we spend identifying foods? What percentage of the foods purchased and what type of foods are marked gluten-free? How are the buying practices of the celiac community influenced by the word gluten-free on a label as opposed with a product with the same ingredients without the words gluten-free?

These questions are just beginning to be

asked in our community. The major grassroots efforts of the celiac community to get the word wheat included in FALCPA and the subsequent conditions of that bill have brought about these meetings. In the past sufficient data has not been available to intelligently answer the questions posed. This information has to be accurate, not anecdotal, and it is just now being collected.

On July 27, in a newspaper article, "Gluten-Free Market Goes Mainstream," it stated that gluten-free products will now be available at Walmart. That is good news. But who made the determination that these products are, in fact, gluten-free? This false sense of food safety is misleading and unfortunate for people who rely on the truthfulness and scientific accuracy of a label.

When a celiac eats a product that is assumed to be gluten-free because the manufacturer says so, without any regulation from the FDA, the results can be great physical distress, as well as emotional upset because what the consumer believed

to be safe has now harmed them.

Those in the celiac community are devoted label readers. Labels that carry the statement that the product was produced in a facility that also makes products containing other allergens as well as wheat is most helpful, calling the consumer to make an informed decision before purchasing the product. Products that are naturally gluten-free do not require the GF label. But all foods that have been processed, blended, combined and determined to be gluten-free must meet the criteria to be set by the FDA.

The FDA has always been a champion in its responsibility for the safety of food products to the public. This is why the FDA unequivocally must be the regulatory agency determining what is gluten-free. It will be the FDA seal that celiacs will trust and depend on when selecting appropriate gluten-free foods. Thank you.

DR. SCHNEEMAN: Thank you, and exactly on time! Good model, folks! The next person?

MR. SULLIVAN: Good afternoon. My name is

Thomas Sullivan. I have the honor of being the president of the Celiac Sprue Association for this year.

I am not myself a celiac. I have a wife who is, a son who is and a great-niece who is. However, if you were to come into our house you would effectively find a gluten-free house. Now, there are four items in the house that are not gluten-free. One is the toaster. There are two toasters on the counter because there is no way in the world that you can avoid cross contact by putting two different types of bagel, bread or anything else in a toaster. So, there is a GF toaster and another. That other one is mine. The two never coexist. There are three other food products in the house that are non-gluten-free. They are bread, cookies and cereal. They don't exist out front. They are underneath the stove.

There is a very simple reason. It isn't that I don't enjoy eating gluten-free; I do, very much so. But products now, compared to ten years ago, are phenomenal. If you were to take the arena

of foods non-gluten-free ten years ago and gluten-free, they didn't meet. If you take those two universes now and overlap them, the center where products are available to both sides are much, much larger than ever existed. So, the gluten-free diet itself is improving.

One quick example, the no-bun button for low calorie products and fast food markets was done by celiacs years before because we came in to say I want that hamburger with lettuce and tomato, no bun. How do we do it? You put it in a box. You give it to me with a knife and a fork and I can eat! That is how it happened. Now you just go in and say low calorie--no problems. So, we had to do what is coming along automatically and this is how the two universes of foods are overlapping.

The thousands of celiac patients that have been involved with CSA over the last 20 years have, in fact, defined gluten-free. When they started out they started to ask the manufacture do you have gluten in your product? Yeah. Okay, I can't have your product. No problems. Then they started to

ask the question do you have gluten in this product specifically? Yeah. Now, wait a minute, you don't make it with corn, you make it with rice. Why are you saying yes? Because that is corn gluten or rice gluten. Okay, let's ask the question the other way. So, they did. What is the source ingredient for your modified food starch? What is the source ingredient for your enzymes? Those questions started to come through and the answers started to become easier for the patients very quickly.

So, the concept of gluten-free is now wheat, barley, rye and oats in a product or in any of their derivatives. By definition and by actuality that has evolved to what is the current definition. No wheat, barley, rye or oats or any other derivatives means gluten-free. I can use it. I have no problems. And, the quickest way and why you have the celiac patient pick up a product and flip it to the ingredients, go down the list--do I see something I don't recognize the ingredient source on, I put it down and I get another product.

If I see the term wheat, barley, rye or oats, I put it down. That is the quickest way.

There are examples of where that occurs with a newly diagnosed patient. We see them all the time, hear them all the time, and I get calls from all over the world. When you start with a newly diagnosed celiac patient, they are in absolute terror. That is this overwhelming wall of don't eat anything with wheat, barley, rye and oats. Okay, what do I do? So, you give them three words and one direction. Your direction is read the label. The words, starch, vinegar, malted extract. Well, what do you mean? Malted extract has malt in it. By definition of the federal government malted extract is from potatoes, rice or corn. It is good for you. Starch, corn. Vinegar, single word vinegar, apples. Life is great. You have three defined words, three source ingredients. If I see them on a label, no problem.

DR. SCHNEEMAN: Tom, your time is up.

MR. SULLIVAN: I do thank you. It has been a great day.

DR. SCHNEEMAN: Thank you so much.

MR. COX: Hello! My name is Matthew Cox and I am a representative of Bob's Red Mill Natural Foods. I want to thank you all for your endeavors, and thanks for the opportunity of letting us come here and give our point of view.

I wanted to clear up one of the questions that was posed to Dennis Gilliam by the panel regarding how we deal with the consumer that has reported to us that a product that we have marketed as gluten-free, they suspect, is contaminated with gluten, and how we deal with that. It is really a pretty simple process. We take it very seriously though and what we do is we communicate with the consumer directly and try to get as much information from them as we can. We want to find out where did they buy the product, what product is it. We definitely want to get the lot numbers because all the products are identified with a lot number that we can track and, you know, look back at the sourcing, and all those sort of relevant details. We get other information from the

consumer, like what other ingredients did you use? You know, we primarily manufacture baking ingredients. So, what did you combine with this flour to make your baked goods? You know, we have no idea how to gauge how well informed they are. Maybe they are using ingredients that they are not aware contain gluten, like an extract, malted barley, or something like that.

After getting as much information as we can, we provide a report to our quality assurance department and that report is then evaluated and, if necessary, we try to acquire a sample from the consumer, maybe a sample of their product so we can compare that with the product that we have in-house. If it is warranted, we also audit the manufacturing process. Again, it is visual inspections and, you know, just a basic run-through to see if there is anything that we are missing, any gaps that have been left open leading to some potential for contamination.

We have only had reports like this--in four years I can only recall maybe a dozen people

reporting that products that we market as gluten-free have caused a reaction in them, and none of them have ever resulted in a recall, or anything like that, which we could implement if we needed to. We would just simply track the entire lot and get all that product back, and that is what we would do if there was such a case. So, I hope that that answers the question for you.

I also wanted to mention that I have talked to a lot of our consumers. We have lots of calls to action, inviting our consumers to give us feedback if they have any questions or concerns at all, and all our literature, all our products are widely open for them to contact us. As a result, we have had many, many conversations with our celiac consumers. I know personally that labeling products gluten-free does make a difference for them. It does make it easier for them to shop for products they need to eat and enjoy life.

We also use a symbol on our products. Yes, it is a marketing device but it also helps consumers. We have many products and many of them

are not gluten-free and we want to make it easy for them to tell which products are gluten-free. So, this symbol that they can notice on the packaging is very useful to them and I have had reports on that from consumers.

I would like the FDA, if possible in the final ruling, to allow for the use of symbols that imply that a product is gluten-free. Also, I might ask that the FDA ban or bar companies from using a symbol that imply gluten-free when that product contains gluten in it. One example might be a manufacturer that makes a spelt bread and might use a symbol that has a grain shaft that is crossed out, which we use and I know other organizations use similar symbols. So, just to limit the level of confusion, and there is plenty of that already for celiac consumers, I might ask the FDA to address those issues. That is it. Thank you.

DR. SCHNEEMAN: Great! Thank you. That was another star performance, within five minutes!

MS. FENSTER: Hello! My name is Carol Fenster, and I am president and founder of Savory

Palate, Inc. For the past ten years I have been providing a cookbook and publishing and consulting information on the gluten-free diet. As the author of six of those cookbooks on gluten-free cooking and developer of gluten-free products for manufacturers, including Bob's Red Mill who is present here today, the importance of correct, consistent labels is critically.

When I formulate a recipe for one of my cookbooks I rely on the ingredient label. When I search the grocery stores or health food stores or go online for hard to find items, I look to see if the ingredient is labeled gluten-free somewhere on the package. I have learned that this label can be very large on some products, even incorporated into the overall design of the package. On other products I have to search very hard for the words gluten-free and sometimes I find them on the back of the package in tiny, little letters. Even then I look at the list of ingredients just to be sure because I know that not all companies use the same criteria, and I have learned to take nothing for

granted.

As I read through the list of ingredients, sometimes I don't even recognize the words and for help I consult a book that has kind of become my bible, "The Consumer's Dictionary of Food Additives: Descriptions in Plain English of More than 8,000 Ingredients, Both Harmful and Desirable, Found in Food." It is kind of a long title to begin with. It is by Ruth Winters. This book does not address gluten-free in any way, shape or form but at least it gives me a working knowledge of what this rather strange ingredient is. Then, for help with other ingredients that I wonder if they are gluten-free or not, I turn to publications like "Gluten-Free Living" which carefully researches many suspect foods, or the "Quick-Start Diet Guide," or all the other manuals that things that were mentioned today. I reference all of those. I also consult lists and where there are constant changes.

Once I have all the information I decide with that ingredient is appropriate to use in my

recipes in my cookbooks. If I decide that it just doesn't meet my criteria, then I simply don't use it. When in doubt, don't use it.

Now, the same process I use for my own recipes and my own cookbooks becomes even more complex when you develop products for corporations because of what we call the sourcing issue. Sometimes the ingredients I must use are not available to me as a general consumer, and I don't have access to the label to read it, or the manufacturer of a consumer ingredient that I buy on the store shelf is not quite the same as the one manufactured by the commercial provider which only other corporations can buy. In other words, certain products out there only other corporations can buy wholesale and have the whole issue of labeling all over again. Whereas, I am a consumer, and I am gluten-free, by the way also, I have learned to rely on very specific lists.

This means that my client needs to source out or to research on my behalf the right sources for ingredients, and not always having access to

all the relevant information, the sources may not be required or may downright refuse to disclose exact ingredients because of proprietary issues. Since many of these sources provide a myriad of products, some gluten-free and some not, there is always the risk of whether there is a cross contamination. So, this all has to be considered.

My concern with these ingredients is only amplified when we talk about more complex processed foods such as certain dairy products, whether yoghurt, sour cream or Worcestershire sauce. By the way, I had an interesting thing happen to me. I was very confident that a certain brand of Worcestershire sauce, here in the U.S., was gluten-free. I specified that brand in my cookbook, only to learn that in Canada that brand is not gluten-free. So, there we are with issues of labeling for us internationally.

At any rate, in summary, I think a standardized set of guidelines about what is gluten-free will help me make recipes that I know are safe for my customers. It will help my

customers locate the same safe ingredients that I specify in my recipes. And, it will give manufacturers guidance in selecting gluten-free ingredients for their products whether they are developed in-house or by consultants such as me.

It is time that we all agree on what gluten-free means and what is not, and implement guidelines that assure a correct, consistent label. Thank you very much.

DR. SCHNEEMAN: Thank you.

MS. ASHWORTH: Hello! My name is Anna Ashworth and I am the vice president of business and administration for the Gluten-Intolerance Group, and I am also a representative for the Gluten-Free Certification Organization. I also have celiac disease.

Cynthia Cooper, the executive director for the Gluten-Intolerance Group, conducted an online consumer survey to get the gluten-free consumers' perspective on issues of labeling, purchasing decisions and determination of what gluten-free means to them. This survey, which was sent to the

FDA on August 15, had nearly 2,100 responses worldwide and confirmed what we already knew, that gluten-free consumers want products that are clearly labeled to be gluten-free and that they know to be free of cross contamination.

Gluten-free consumers would benefit from a gluten-free certification program and manufacturers would benefit from their consumers' increased confidence in their products. To meet these needs, over the past two years the Gluten-Intolerance Group, in conjunction with a committee of scientific advisers, has worked to develop an independent certification program for gluten-free food processing. This program, the Gluten-Free Certification Organization, or GFCO, is the first program of its kind in the world. GFCO was developed in cooperation with Food Services, Inc., a subsidiary of the Orthodox Union, the world's largest and oldest kosher certification agency, with food inspection agents all over the world.

Key elements of the GFCO process will include the following: Individual ingredients will

be reviewed down to the original supplier. There will be on-site inspections by independent, experienced, specially trained field inspection agents provided by the global resources of Food Services, Inc., a subsidiary of the Orthodox Union. Products and ingredients will be tested using scientifically proven AOAC approved test methods.

There will be regular spot plant visits and product testing by field inspection agents. The GFCO certification mark will appear on product packages for easy identification. The manufacturer and the Gluten-Free Certification Organization have a written agreement that states what can go into the product and how it is produced. The GFCO must be consulted in advance of any ingredient or processing changes to ensure that the product's gluten-free status is not affected. As a global program, the GFCO uses the highest standards for gluten-free ingredients and a safe processing environment based on a continual review of the current scientific and testing methodologies, existing global standards such as Codex in Canada,

and balanced by reasonable application by the manufacturer.

A new Gluten-Free Certification mark on food labels will allow gluten-free consumers to eat easily and confidently, identify safe food that has been independently verified to meet the highest standards for gluten-free. We already have food manufacturers who have signed on with the GFCO program and we have received enthusiastic interest from many more. We are providing this program on behalf of the community who have voiced their strong interest in having gluten-free certification. Our standards are always available for public inspection on our website, www.gfco.org. Thank you.

DR. SCHNEEMAN: Thank you.

MR. BROWNE: Hello there! Thank you for allowing me to speak. My name is David Browne. I work for a company called SPINS. We are a San Francisco-based organization. I am the director of content services there.

SPINS is a leading provider of information

to the natural products industry. Specifically what we do, we track the sale of bar coded products moving through natural supermarkets, including Whole Foods and Wild Oats and many independent stores. We also track the sale of natural and organic products moving through conventional supermarkets such as the Safeway and other drug stores.

Through this, in the last several months we started tracking gluten-free products specifically and flagging them in our database of over 400,000 products. I wanted to use my time today to provide some top-line information, statistical information on what we found with gluten-free products.

First of all, my team calls manufacturers and checks product websites to identify products that are marketed and claim on their labels that they are gluten-free. In instances where it is not labeled, we are still talking to the manufacturer to ask some other information. Generally, we found that there are about three buckets that companies

that are making gluten-free products fall into. One is that their product is gluten-free and it is labeled as such. Two, the product is gluten-free but it is not labeled as such and in general the reply is that with the new labeling that they are going to be generating, new labels will have that but they have to go through their existing labels before they move forward. Thirdly, the product is gluten-free but they will not guarantee it, for all the reasons that we talked about earlier today as far as cross contamination and manufacturer warehousing where they are storing these goods. In the case of that, we are only coding items that are actually labeled as gluten-free at this point.

First off, I just want to summarize what we have found. We have researched over 10,000 products that fall into food categories where gluten-free products are known to exist, categories like bread and baked goods, cookies, cereals, frozen entrees, and other categories such as soup and candy where product labeling for gluten-free is common. At this point we have identified over

2,000 products moving in the U.S., with sales over 600 million dollars. This is a growth of 1.6 percent year over year, and that is both channels, both natural supermarkets and conventional supermarkets combined.

As far as UPC codes go, the vast majority of the are still moving in natural supermarkets. There are over 2,000 that are moving in natural supermarkets at this point. That is an increase of 9 percent over last year when there were over 1,965 items that were labeled as gluten-free. In the conventional channel there are about half, there are only about 1,200 items at this point that are labeled as gluten-free but, because of the volume of sales that occur in conventional, that 600 million dollar figure is broken down into being 400 million approximately moving in conventional supermarkets and 200 million moving in natural supermarkets.

For today's session I tried to encapsulate just about 9 categories where there is a lot of activity both in volume and quantity of UPCs. The

9 categories include, as I say, chips and snacks, puddings and desserts, entrees and mixes, cookies, soup, baking mixes and supplies, bread and baked goods, frozen entrees and candy. In the natural channel sales are growing for these gluten-free products at 12 percent. In the conventional channel they are growing at 17.8 percent. That may seem ironic but, in fact, as a lot of us know, gluten-free products have long been available in natural product supermarkets and what is happening over the last several years is that they are migrating into the conventional channel. Because of that, their growth rates are much larger and their volume.

One of the other interesting points that I want to mention today is that when you take some of these categories as a whole and look at their growth rates, and then look at the gluten-free products that are labeled within that and look at their growth rates, the gluten-free products far exceed the growth of the category as a whole. Essentially, they are driving the growth of the

category.

Take a category like candy for example, which had a lot of up and down last several years due to low carb diets and products like Atkins bar on the market which were essentially candies but they were sugar-free version, the category is still showing positive growth in the natural channel at about 22 percent, but gluten-free candy is growing at 47 percent. Take a category like baking mixes and supplies, the category is relatively flat in the natural channel about 5 percent growth; gluten-free products are growing at 18.6 percent growth.

DR. SCHNEEMAN: We do need you to wrap up, but this sounds like the kind of data that would be great to submit to us.

MR. BROWNE: I have already submitted it, yes. I just want to say one last thing. Another important element of the growth of gluten-free products is that the share of the total sales for gluten-free products within a category is increasing year over year. If you take a category

like baking mixes and the share of total sales within that category for gluten-free products went from 36 percent last year to 39 percent this year. So, more consumers are buying baking mixes and supplies that contain gluten-free products in volume than they were a year ago. Thank you very much.

DR. SCHNEEMAN: Thank you.

MS. WHELAN: My name is Ann Whelan, and together with Amy Rettner I have published "Gluten-Free Living," a national magazine for people who have celiac disease, for the last ten years. Over those years we have concentrated our research efforts on ingredients and their relation to celiac disease.

I was asked to respond to questions eight, nine and ten. Question eight, are there available research data or findings on what consumers with celiac disease or their caregivers believe the term gluten-free means? For example, do the research data or findings show consumers' belief as to what specific grains or other ingredients are not

present in foods labeled gluten-free?

I believe there are at least two ongoing research studies as we speak, and from what I have heard today there are probably more. We did a survey nine years ago and some of the results of that survey are relevant to question nine. But we are planning on another survey which will probably be presented in our next issue, and in the new climate of celiac disease which is much different than it was nine years ago, I am very curious to see what we will find out.

You ask what people think the term gluten-free means. In the current climate it would be difficult for people to explain what they think gluten-free means. The reason it would be difficult is found in the second part of your question, meaning disagreement within the celiac community over specific grains and specific ingredients that are gluten-free. The specific grains part of the question is more easily addressed, and you have heard it today. Everyone agrees on wheat, rye and barley as grains not being

found in foods marketed as gluten-free and, as everybody else said, at this point I think people expect oats to be in that category too. We have spelt, kamut and triticale that aren't found that much. Spelt is a problem. In the past, and you have heard this, some spelt companies have said spelt is safe for people who are sensitive to gluten, and it is still not clear, at least on one spelt site, that spelt is not safe for anybody who has celiac disease. So, any definition of gluten-free would have to emphasize that the product does not contain spelt. Most celiacs recognize corn, rice, potatoes and tapioca as being gluten-free. Uneasiness about some of the alternative grains like buckwheat and kimwa seems to have been addressed now and everybody is cool I think on that issue.

The ingredients portion is much less easily resolved. First, many celiacs do not know who to believe. There is a lot of information out there that seems to have been put forward on the basis of no evidence whatsoever. Some of our

readers ask us you say this, but I read that elsewhere. At this point I explain to them how we do our research and recommend that they go back to the other source and find out how they do their research. For the record, we do our research by querying the people who should know the answers to the questions. We include the FDA, the USDA grain scientists, ingredient makers, food processors, food companies and other relevant sources of that ilk. Over nearly ten years we have developed a relationship with these groups and, therefore, have a place to start when we begin researching something new.

Second, people do not understand what certain ingredients are, and for good reason. For example, malt comes from barley and, therefore, would not be included in a product labeled gluten-free. Dextran can be derived from several grains, one of which is wheat. So, a product labeled gluten-free wouldn't contain dextran derived from wheat. Malt dextran, on the other hand, as you heard, is gluten-free. However, it if

comes from outside the United States, and even sometimes from inside the United States, it may contain wheat but it will be wheat malt dextran or malt dextran wheat.

Now, I can explain that quickly because I have done in-depth research on many ingredients. But when you are used to picking up a product off a shelf and throwing it into your shopping cart, and on top of that you know that some of these products and ingredients are going to make you sick, the learning curve required to be comfortable and efficient and effective with the diet is daunting. We are currently working on a booklet of ingredients and I hope that will help people make safe decisions.

We work very hard to explain ingredients as clearly as possible but ingredients are what they are and some explanations are complex. In fact, I suspect the complexity of the diet is the main reason why most people we ask say just tell me if the product is gluten-free. Just tell me what can I eat. We asked over the last two weeks what

people would like to see and everybody told us some version of the same thing. Make it easy to read. I hate to have to read a label forever. I want the label to specifically say gluten-free. I don't want to have to assume it is gluten-free just because it doesn't contain wheat. Just tell me plain and simple gluten-free.

Third, people are afraid of what they don't know, especially if they have been very sick. That is understandable. The fear is amplified by misinformation that suggests molecules of gluten are dangerous or tries to define the diet by brands versus ingredients, and that is kind of a complex issue that I won't go into. But an acceptable agreement on what gluten-free means when it appears on the label would solve that problem.

Fourth, people perceive some ingredients as being gluten-free some of the time and not gluten-free other parts of the time, and that is truly confusing. Starch is a good example. Starch and food starch on a food label mean corn starch. Modified food starch may, and usually does mean

modified corn starch. The FDA regulation on this ingredient is currently understood as saying modified food starch could be modified anything starch.

DR. SCHNEEMAN: Ann, we need to finish up.

MS. WHELAN: Okay. I think that it is doable right now for us to define the gluten-free diet and to solve all of these ingredient problems. It is my humble opinion that we need a better agreement on the specific grains and ingredients that would be excluded from a product label of gluten-free before you can regulate the use of the term gluten-free on a food label. I offer our ten years of research to anybody that would like it in order to determine this.

DR. SCHNEEMAN: That would be great, and I hope you do submit that to the docket.

MS. WHELAN: Fine. Thank you.

DR. SCHNEEMAN: Thank you.

MS. BAST: My name is Alice Bast and I am the founder and the executive director of the National Foundation for Celiac Awareness. I want

to say that Ann Whelan has incredible information. The information I am presenting today is customer surveys. Her information is scientifically vetted.

On behalf of the of the Americans who suffer from celiac disease, I appreciate the opportunity to provide information on consumer understanding of the term gluten-free and the purchasing practices of celiac patients and their caregivers in the public meeting on gluten-free labeling.

The National Foundation prepared a short survey which was posted on our website and was e-mailed to support group members around the country. We received informative and heartfelt responses to the seven questions that were developed based on questions eight, nine and ten in the Notice for today's public hearing. We will submit the full responses in part of our written comments and I will summarize the results today.

The respondents are educated consumers that spend considerable time and effort in educating themselves and researching the contents

of the food they buy in stores and eat in restaurants. They rely on the gluten-free label and express to us and the food manufacturers who have policies not to hide allergens and gluten. When given a choice, they buy products that are labeled gluten-free over those that are not. They are thrilled that the food labeling will soon be improved because it will save time, reduce frustration and provide a measure of confidence that they and their families are eating foods that are safe.

The following are the questions we asked and a summary of the responses we received. What does the term gluten-free mean to you? The overwhelming response was that gluten-free means gluten-free, that is, the product contains no wheat, barley, rye and related grains and derivatives. A few mention above a safe threshold but the general respondents expressed an understanding that no gluten is present in the food product either directly or as a result of cross contamination and, again, there was confusion over

spelt and oats.

How do you identify foods that do not contain gluten? The primary response was read the label, followed by calling or e-mailing manufacturers, food lists from select support groups, reference provided by medical providers, newsletters and the internet. Often people read labels and call manufacturers to confirm, having learned about cross contamination potential and changing manufacturing practices as the hidden source of gluten. Many mentioned calling the manufacturer in the grocery store in order to be able to make a safe purchase. Respondents expressed the need to look for ingredients which are derivatives of wheat, barley and rye and other ingredients which contain these in reality but not in their names. Also, many said fear played a role. They are worried about buying products when they didn't recognize the name so they would automatically not buy those products because they weren't sure whether they contain gluten or not. Many mentioned the difficulty in eating out safely

because restaurants don't always know whether gluten is contained in the bulk ingredients that they buy.

How much time to you spend identifying gluten-free foods? The response to this question varied. Some folks indicated that they are educated and they carry lists with them and just buy the same foods again and again. Others spend 30 minutes extra each week reading labels and researching ingredients. Others said that grocery shopping takes twice as long as normal.

Many have come to rely on the current gluten-free label as a time saver and seek out brands from companies who have voluntarily made allergen and gluten information available in their packaging. Most expressed the need for a uniform label so it would be faster and easier for them to obtain the information.

Four, when you purchase packaged foods, do you purchase foods that are primarily or exclusively labeled gluten-free? Many respondents indicated that they do prefer to purchase products

that are labeled gluten-free if available. They also indicated that they must purchase products that are not labeled and, in order to do so, must read the ingredient lists. Many mentioned the added expense of products that are labeled gluten-free.

Five, if so, what types of packaged foods that are labeled gluten-free do you purchase? For example, breads, dairies, canned vegetables, and there is a whole list of a variety of products that they do purchase.

Does a gluten-free label influence your purchasing decision when you have a choice among products having identical ingredient lists? The overwhelming response was yes. People indicated they felt confident that the food was safe for them to eat if it had a gluten-free label.

Seven, would you like to share any other thoughts about a need for accurate understanding of food labeling in your experience with food labeling? The overwhelming response was that people are looking forward to having clear,

unambiguous food labeling so they could be sure the food they were planning to eat was, in fact, gluten-free and, therefore, safe. Many expressed the challenge of complying with the gluten-free diet when labels do not clearly indicate whether gluten is present.

In conclusion, as the NFCA analyzed the responses to our survey, we reinforced our own belief that clear, unambiguous labeling of food is a win-win for everyone-- celiac disease patients and food providers throughout the food chain. People with celiac disease will save time and will greatly improve their ability to select foods that are safe to eat. Food providers, by clearly indicating whether gluten is present in the foods they produce or serve, will engender the trust of celiac sufferers and, therefore, create loyal consumers for their brands. Thank you for the opportunity to speak with you today.

DR. SCHNEEMAN: Great! Thank you.

MS. KUJO: Hi! My name is Jill Kujo. I am here representing Whole Foods Market. My

official title is research and customer relations coordinator. That means I answer the phones, answer all the e-mail and I also talk to our ingredient suppliers. I collect the letters of certification.

I really wanted to bring out that while we focus a lot on the breads and cakes and desserts that celiacs can't eat, there are a lot of general grocery products that people don't think of right away as containing gluten, deli meats, snack foods, spices, mixes. A lot of times when I am getting initially diagnosed people write to me, I inform that these products are available in our stores and it is more often the smaller producers that will make products, like potato chips, that don't have gluten in the spice mix that goes on them.

I think that although perhaps our ignorance in this country about celiac disease may be a reason why there are cross contamination issues, especially in oats. I also think it might be because I get the general impression that we process our foods a little bit more than the rest

of the world and gluten is really useful in processing, not only to tie things together like in baking but also to keep spices from clumping in production. I think that is it. Thank you.

DR. SCHNEEMAN: Great! Thank you.

MR. BLANK: My name is James Blank. I am a member of CSA. I just wanted to bring out that the gluten-free labeling is going to help some people that are very vulnerable, and those are the very elderly people and the very young. Most of the time that has to do with the caregivers and families that have to try to figure out this whole thing about gluten-free or not.

I was diagnosed 12 years ago and I was doing fine. Eight months ago my father was diagnosed with celiac disease. Now I have to teach my family and, you know, his wife how to look for gluten-free products and it is very difficult, especially when you have some family members that don't understand celiac disease and how difficult it is and how dangerous it can be for people. When I was diagnosed I lost 50 lbs. and I almost died

from this disease. I think that is the thing, and when you are diagnosed with something and you get very sick from it, you know, it really matters. Now, with my father, 78 years old now, it is hard. I have to train him, 78 years old and now he has to learn how to eat all over again.

I think these are the people that the gluten-free labeling is going to help. Those and also people in hospitals. You know, people are afraid. They are afraid to go to the hospital because they don't know what they are going to eat. So, that is all I have to say and I just want to thank the FDA for having this meeting.

DR. SCHNEEMAN: Great! Thank you. Do we have any other presenters?

[No response]

Again, on behalf of FDA, I want to really sincerely express my appreciation to all of you who have been here today for your participation and involvement. I appreciate the fact that you have respected our time schedule; you have respected the fact that we had very specific questions that we

are trying to address and I think you have provided us with a real wealth of information. Again, hearing from both the industry as well as consumers, plus the analytical piece of it, those are all important inputs for our decision-making.

Before we adjourn, I do want to remind everyone of the docket number, 2005N-0279 that corresponds to this meeting. The ten questions that we cited in the Federal Register Notice will remain there and that docket is open until September 19. Obviously, we have heard in just short presentations that some of you do have additional data, references, reference material and perhaps some additional comments. So, we encourage you to submit material to that docket and that is one of the best ways to make sure that FDA considers your input in its decision-making as it goes forward with this very important initiative.

So, again, thank you for being here. Thank you for sticking to the very end so that we had the opportunity to hear everyone who wanted to make a comment. I just want to express my sincere

appreciation to the staff at FDA who really worked hard to put all of this together, to gather the speakers, arrange the meeting. I know that Rhonda Kane has spent a substantial amount of time, and Geraldine June has also put in a huge effort to make sure that this meeting would come off very well and that FDA would be able to gather the type of information that is most useful to us. We had a lot of volunteers from our office who have helped with the registration desk. That is just extra effort on their part because they view this information as important. So, again, thank you for being here.

[Whereupon, at 4:08 p.m., the proceedings were adjourned.]

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